

REMARKS

Claims 13, 8-13, 15-24, 26-28, 30-32, 34-37, 40, 41, 43, and 45-49 are pending in the application, claims 2, 4-7, 14, 25, 29, 33, 38, 39, and 44 being canceled and claims 45-49 being newly added herein. Claim 42 was canceled previously. Claims 1, 15, 22, and 24 are the only independent claims.

Claims Rejections - 35 U.S.C. §§ 102 and 103

Claims 1-5, 12-16, 20, 21, 23-25, 33 and 37-41 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,585,642 to Christopher.

Claims 6, 8, 9, 17-19, 29, 32, and 34-36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Christopher in view of U.S. Patent No. 5,257,617 to Takahashi.

Claims 7 and 26-28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Christopher in view of U.S. Patent No. 4,866,049 to Darras.

Claims 10, 11, 30, and 31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Christopher in view of U.S. Patent No. 5,817,015 to Adair.

Claims 22 and 43 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Christopher.

Claim 1 Applicant has amended claim 1 herein to incorporate subject matter from dependent claim 8. Claim 1 is now directed to a feature of applicant's invention depicted in Figure 7 of the disclosure. Applicant respectfully maintains that amended claim 1 distinguishes the invention over the prior art and particularly over the art relied on by the Examiner in rejecting the claims of the instant application.

As set forth in amended claim 1, a flexible endoscope comprises a flexible elongate insertion shaft formed along an outer surface with at least one longitudinally extending channel having a transverse dimension or diameter. The channel has a longitudinally extending slot through the outer surface of the endoscope insertion member, the slot having a transverse dimension or width. The transverse dimension or width of the slot is smaller than the transverse dimension or diameter of the channel. The endoscope further comprises at least one closure member removably connected to the insertion shaft to close the slot, the insertion shaft being formed with a pair of opposing edges along the slot and the closure member being removably attached to the insertion shaft at the edges of the slot.

Neither Christopher nor Takehashi discloses or suggests an endoscope having a closure member attached to an insertion member along edges of a longitudinal slot in the insertion member. Accordingly, applicant respectfully traverses the rejection of claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Christopher in view of Takahashi and maintains that amended claim 1 distinguishes applicant's invention over those references.

Christopher and Takahashi disclose the use of a flexible sheath to hold a catheter in an open channel extending longitudinally along an endoscope insertion member. However, this method of holding a catheter in an open working channel has some disadvantages, which are overcome by applicant's invention as set forth in amended claim 1 or as shown in Figure 7.

While Christopher refers only to a suction channel, applicant refers to one or more channels that may also be used for the insertion of working instruments.

Oftentimes endoscopists insert an instrument through a biopsy channel when the endoscope is being flexed or bent inside the gastrointestinal tract, which has a curved lumen. Moreover, oftentimes endoscopists have to retroflex (bend into a sharp U shape) the endoscope all the way in order to look back upon an area from where the endoscope emerged. For example, when an endoscope emerges from the esophagus and into the stomach through the gastroesophageal junction, it is very important and routinely performed to retroflex the endoscope in order to view the gastroesophageal junction from within the stomach. This junction between esophagus and stomach, viewed from below (from the fundus of the stomach), is an area where cancers are often hidden, and may be easily missed if the endoscope is inserted only straight on. Other places where the endoscope is retroflexed during a procedure is in the rectum in order to look carefully for rectal cancer at the anal verge, or when taking out a difficult polyp that can not be approached head on.

When the endoscope described in the Christopher 6,585,642 reference is retroflexed, any catheter disposed in the longitudinal channel would surely pop out even if the catheter were only used for suction. The catheter would certainly pop out if an instrument were passed through it. It is crucial to ensure that any disposable catheter placed in a longitudinal open channel of an endoscope is sealed along its length in such a manner that the catheter is safely locked into its channel. Applicant's invention (Figure 7) accomplishes this through a "door" of sorts. It is even most important in the case where the channel is used for the deployment of working instruments. If one were to push an instrument such as a snare or biopsy forceps through the channel in the '642 Christopher patent while the endoscope were retroflexed, or even bent, the instrument

would be pushing in a straight up and down manner. Unless the channel is safely closed, the instrument would surely push the catheter out of the open channel of the endoscope.

If there were to be more than one such channel, and more instruments were to be pushed through, there would be a mess of loose and bulging tubes all over the intestinal lumen. What is of even more concern about the '642 Christopher channel is that if an instrument were to push through, or even if there were a sharp bulge created because of the above-mentioned situation, a perforation in the colon could easily ensue. This would occur most commonly in a colon with ulcerative colitis, where the colon wall, which when normally measures 1/2 cm in thickness, becomes even thinner and much more soft and friable. In addition, if such a bulge would occur at a place where a sessile (broad) polyp were removed by cautery (electrical burning), a location quite vulnerable for perforation, the same complication could occur.

It is therefore most important for this invention to be practiced that the catheter that forms an additional channel be safely locked into place in its groove until the endoscope is withdrawn from the patient, and the endoscope is ready for washing and sterilizing.

Claims 15, 22, and 24 have been amended similarly to claim 1 and distinguish, for reasons set forth above, over the newly cited Christopher, alone or in combination with Takahashi.

The specification has been amended to provide antecedent basis for new claims 45-49. The additional language describes features shown in the drawings (Figure 7) and accordingly no new matter has been added.

The claim amendments, if any, made herein are made without prejudice to applicants' right to pursue additional subject matter in a separate continuation or divisional application.

Conclusion

For the foregoing reasons, independent claims 1, 15, 22, and 24, as well as the claims dependent therefrom, are deemed to be in condition for allowance. An early Notice to that effect is earnestly solicited.

Should the Examiner believe that direct contact with applicant's attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

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